

MAY 14 2001

K003122

510(K) SUMMARY

SmartFlow™

510(k) Number K_____

Applicant's Name:

Florence Medical Ltd.
Sharona Center
12 Derech Hasharon
Kfar-Saba, Israel
Tel.: 972-9-7431975
Fax: 972-9-7452323
SmartFlow@florence.co.il

Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
Fax: 972-9-7718131

Date Prepared:

Septmber 2000

Trade Name:

SmartFlow™

Classification Name:

Programmable Diagnostic Computer

Classification:

The FDA has classified Programmable Diagnostic Computer as class II devices (product code 74 DQK, Regulation No. 870.1425) and they are reviewed by the Cardiovascular Panel.

Predicate Device:

- Cardiometrics Flowire/Flomap System cleared under K912776
- Cardiometrics WaveWire/WaveMap Pressure Guide Wire System, cleared under K965140

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the SmartFlow™ complies with voluntary standards IEC 60601-1+A1+A2; UL 2601-1; EN 60601-1-2; EN 55011; EN 61000-4-2/3/4/5; EN-1441.

Intended Use:

The SmartFlow™ is intended for use in coronary and peripheral vasculature in conjunction with pressure measurement devices during and after diagnostic procedures, such as angiography, or interventional procedures, such as angioplasty, to evaluate the hemodynamic status of the diseased arteries and to provide further clinical information in the diagnosis and treatment of both coronary and peripheral artery diseases.

Device Description:

The Smart Flow™ provides a novel method for calculating the flow-based clinical characteristics, CFR in addition to the FFR, using pressure measurements across a stenosis.

The SmartFlow™ is a PC based system comprising a color display with a touch-screen for patient data entry and control, and software calculations of the CFR and FFR parameters.

The SmartFlow™ may be operated through its touch-screen or through an infrared receiver port, which allows the use of a hand-held remote control.

The SmartFlow™ complies with all applicable IEC regulations for product safety and emissions for use in a Catheterization Laboratory environment.

Substantial Equivalence:

Florence Medical Ltd. believes that, based on calculations, validations, and performance testing results, the SmartFlow™ is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2001

Ms. Shoshana Friedman
Florence Medical Consultant
c/o Push-Med Ltd.
117 Ahuzah Street
Ra'ananna 43373
ISRAEL

Re: K003122
SmartFlow™
Regulation Number: 870.1110
Regulatory Class: II (two)
Product Code: 74 DSK
Dated: February 12, 2001
Received: February 13, 2001

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

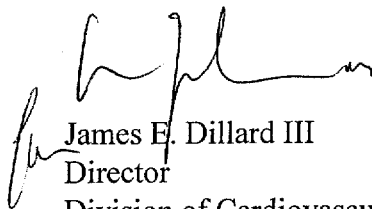
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name and title.

James E. Dillard III
Director

Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

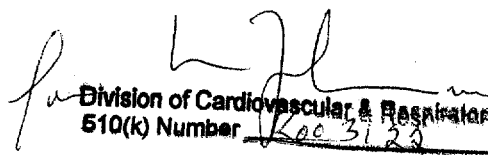
Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003122

Device Name: SmartFlow™

Indications for Use: The SmartFlow™ is intended for use in coronary and peripheral vasculature in conjunction with pressure measurement devices during and after diagnostic procedures, such as angiography, or interventional procedures, such as angioplasty, to evaluate the hemodynamic status of the diseased arteries and to provide further clinical information in the diagnosis and treatment of both coronary and peripheral artery diseases.


Division of Cardiovascular & Respiratory Devices
510(k) Number K003122

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over the Counter Use _____